



Receipt

DOCKET NO. MUR-039-USA-PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

K. Mori, et al.

Serial No.: **10/501,946**

Art Unit: **3762**

Filed: **July 21, 2004**

Examiner: **To Be Assigned**

For: **Preparation For Transdermal Or Transmucosal Administration For Electroporation**

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants' counsel is in receipt of the PTO Filing Receipt for the above identified pending patent application, a copy of which is attached hereto. Upon verifying the accuracy of the data presented on the Filing Receipt it was noted that there are errors in the title for this invention which were introduced by the Patent Office. As evidenced by the attached copy of the Transmittal, Declaration and Power of Attorney, and first page of the original specification which contains the title, the title should be "**Preparation For Transdermal Or Transmucosal Administration For Electroporation**" rather than "Transdermal/transmucosal preparations for electroporation" written on the Filing Receipt.

It is respectfully requested that the Patent Office records be corrected to reflect the correct title and that the undersigned be provided with a corrected Filing Receipt.

Respectfully submitted,

Donald E. Townsend, Jr.

Donald E. Townsend, Jr.
Reg. No. 43,198

Customer No. 27955

Date: January 11, 2005

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPL NO.	FILING OR 371 DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/501,946	07/21/2004	3762	920	MUR-039-USA-PCT	2	12	2

CONFIRMATION NO. 8460

Townsend & Banta
601 Pennsylvania Avenue NW
Suite 900 South Building
Washington, DC 20004

FILING RECEIPT



OC000000014775461

Date Mailed: 12/22/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Kenji Mori, Tsukuba-shi Ibaraki, JAPAN;
Seiji Tokumoto, Tsukuba-shi Ibaraki, JAPAN;
Naruhito Higo, Ibaraki, JAPAN;
Shuji Sato, Kanagawa, JAPAN;
Kenji Sugibayashi, Saitama, JAPAN;

Power of Attorney:

Donald Townsend-22069

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/JP03/00412 01/20/2003

Foreign Applications

JAPAN 2002-15378 01/24/2002

Projected Publication Date: 03/24/2005

Non-Publication Request: No

Early Publication Request: No

Title

Transdermal/transmucosal preparations for electroporation

Preliminary Class

607

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

APPLICATION NO. (if known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.
PCT/JP03/00412

INTERNATIONAL FILING DATE
January 20, 2003

PRIORITY DATE CLAIMED
January 24, 2002

TITLE OF INVENTION Preparation For Transdermal Or Transmucosal
Administration For Electroporation

APPLICANT(S) FOR DO/EO/US Kenji Mori, Seiji Tokumoto, Naruhito Higo,
Shuji Sato and Kenji Sugibayashi

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☒ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Claim for Priority

21. ☒ The following fees are sur- cu:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):

Neither international preliminary examination fee (37 CFR 1.482)
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO
and International Search Report not prepared by the EPO or JPO. \$1080.00

International preliminary examination fee (37 CFR 1.482) not paid to
USPTO but International Search Report prepared by the EPO or JPO \$920.00

International preliminary examination fee (37 CFR 1.482) not paid to USPTO
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$770.00

International preliminary examination fee (37 CFR 1.482) paid to USPTO
but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$730.00

International preliminary examination fee (37 CFR 1.482) paid to USPTO
and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT =

\$ 920.00

Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months
from the earliest claimed priority date (37 CFR 1.492(e)).

\$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims	12 - 20 =	-0-	x \$18.00	\$
Independent claims	2 - 3 =	-0-	x \$86.00	\$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$290.00	\$

TOTAL OF ABOVE CALCULATIONS =

\$ 920.00

☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above
are reduced by 1/2.

\$

SUBTOTAL =

\$ 920.00

Processing fee of \$130.00 for furnishing the English translation later than 30 months
from the earliest claimed priority date (37 CFR 1.492(f)).

\$

TOTAL NATIONAL FEE =

\$ 920.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +

\$ 40.00

TOTAL FEES ENCLOSED =

\$ 960.00

Amount to be
refunded:

\$

charged:

\$

- a. ☒ A check in the amount of \$ 960.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
overpayment to Deposit Account No. 20-1424 A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card
information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a)
or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

TOWNSEND & BANTA
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SIGNATURE

Donald E. Townsend
NAME

22,069
REGISTRATION NUMBER

PREPARATION FOR TRANSDERMAL OR TRANSMUCOSAL ADMINISTRATION
FOR ELECTROPORATION

FULL NAME OF THIRD JOINT INVENTOR, IF ANY HIGO, Naruhito	INVENTOR'S SIGNATURE <i>Naruhito Higo</i>	DATE May 6, 2004
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN		CITIZENSHIP JAPANESE
POST OFFICE ADDRESS		

FULL NAME OF FOURTH JOINT INVENTOR, IF ANY SATO, Shuji	INVENTOR'S SIGNATURE <i>Shuji Sato</i>	DATE May 6, 2004
RESIDENCE Greenhawks A-104, 1-11-5, Arima, Miyamae-ku, Kawasaki-shi, Kanagawa 216-0003 JAPAN		CITIZENSHIP JAPANESE
POST OFFICE ADDRESS		

FULL NAME OF FIFTH JOINT INVENTOR, IF ANY SUGIBAYASHI, Kenji	INVENTOR'S SIGNATURE <i>Kenji Sugibayashi</i>	DATE May 6, 2004
RESIDENCE 14-46, Arajyuku-machi 1-chome, Kawagoe-shi, Saitama 350-1124 JAPAN		CITIZENSHIP JAPANESE
POST OFFICE ADDRESS		

FULL NAME OF SIXTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

FULL NAME OF SEVENTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

FULL NAME OF EIGHTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

FULL NAME OF NINTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

FULL NAME OF TENTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PREPARATION FOR TRANSDERMAL OR TRANSMUCOSAL ADMINISTRATION
FOR ELECTROPORATION

the specification of which is ☒ attached and/or ☐ was filed on as Application Serial No. and was amended on (if applicable)

☒ international (PCT) application No. PCT/JP03/00412 filed Jan. 20, 2003 and as amended on (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE OF FILING	PRIORITY CLAIMED UNDER 35 U.S.C. 119
JAPAN	2002-15378	Jan. 24, 2002	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION NUMBER	DATE OF FILING	STATUS (Patented, Pending, Abandoned)

I hereby appoint the following attorneys to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Law Offices of Townsend & Banta: Donald E. Townsend, Registration No. 22,069; ~~Thomas P. Banta, Registration No. 22,069~~ and Donald E. Townsend, Jr., Registration No. 43,198
Please address all correspondence to the Law Offices of Townsend & Banta, 601 Pennsylvania Avenue, N.W. Suite 900, South Building, Washington, D.C. 20004

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF SOLE OR FIRST INVENTOR MORI, Kenji	INVENTOR'S SIGNATURE <i>Kenji Mori</i>	DATE May 6, 2004
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN		CITIZENSHIP JAPANESE
POST OFFICE ADDRESS		
FULL NAME OF SECOND JOINT INVENTOR, IF ANY TOKUMOTO, Seiji	INVENTOR'S SIGNATURE <i>Seiji Tokumoto</i>	DATE May 6, 2004
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN		CITIZENSHIP JAPANESE
POST OFFICE ADDRESS		

Listing of Inventors Continued on Page 2 hereof. ☒ Yes ☐ No

LAW OFFICES OF TOWNSEND & BANTA • WASHINGTON, D.C.

SPECIFICATION

PREPARATION FOR TRANSDERMAL OR TRANSMUCOSAL ADMINISTRATION
FOR ELECTROPORATION

5

TECHNICAL FIELD

The present invention relates to a preparation for transdermal or transmucosal administration for electroporation for administering from the skin or mucous
10 membrane a compound to be administered (physiologically active substance), such as a drug, using electroporation.

BACKGROUND ART

Electroporation is a method conventionally used in gene
15 transfer, in which a high voltage is momentarily applied to a cell to introduce DNA and the like into the cell. In recent years, the application of this technique to transdermal or transmucosal drug delivery has been proposed (National Publication of International Patent Application No. 3-502416,
20 Proc. Natl. Acad. Sci. USA, 90:10504-10508 (1993)). In this technique a pore is generated in the skin or mucous membrane by a voltage applied between a positive and negative electrode, and the new reversible route (pore) created by this electroporation augments membrane (skin, mucous membrane)
25 transport of a substance. David A. Edwards et al. (Journal of Controlled Release, vol. 34, p211, 1995), A. Jadoul et al. (Journal of Controlled Release, vol. 54, p265, 1998), and Rita